Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 15-01982-113

Healthcare Inspection

Alleged Inappropriate Opioid Prescribing Practices Rutherford County Community Based Outpatient Clinic Rutherfordton, North Carolina

September 29, 2016

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to allegations about inappropriate opioid prescribing practices at the Rutherford County Community Based Outpatient Clinic (CBOC), Rutherfordton, NC, which is associated with the parent facility, Charles George VA Medical Center, Asheville, NC. Specifically, the anonymous complainant alleged that two physicians at the CBOC were being forced to prescribe narcotics to patients that they only see once per year.

We did not substantiate that CBOC physicians were being forced to write prescriptions for opioids, as none of the primary care providers (PCPs) or clinical support staff reported coercion. However, we found that at least one physician, who had recently assumed a full panel of patients, felt pressured to continue another provider's treatment regimen without reassessing the patients in a follow-up visit. Processes at the clinic did not allow for optimized pain management care, and the new provider ultimately resigned.

We identified challenges with the clinical environment in which CBOC providers prescribe opioids and manage the pain-related needs of their patients. We noted a lack of non-opioid pain management options for outpatients. However, they have since opened the Veterans' Integrated Pain Management Clinic at the parent facility and increased staffing and access to non-opioid pain management options. We also found increased administrative demands for PCPs due to new regulatory requirements and communication concerns that affect quality care.

We recommended that the facility Director ensure that:

- PCPs are able to assess, treat, monitor, and reassess patients on chronic opioid therapy within the appropriate timeframe.
- The Veterans' Integrated Pain Management Clinic meets non-opioid pain management needs of patients as evidenced by timely consultation completions.
- Clinical and administrative demands of chronic opioid therapy care are considered when determining appropriateness of PCP staffing and that staffing plans are in place for planned and unplanned provider vacancies and absences.
- Benzodiazepine appropriateness evaluations are completed as required for chronic opioid therapy patients with post-traumatic stress disorder (PTSD).
- Primary care and mental health providers communicate and coordinate care for PTSD patients receiving both opioids and benzodiazepines.
- Regular communication occurs between facility leadership and CBOC leadership to support consistent high quality care.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided acceptable action plans. (See Appendixes A and B, pages 16–20, for the Directors' comments.) We consider Recommendations 1 through 6 closed.

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Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations concerning inappropriate opioid prescribing practices at the Rutherford County Community Based Outpatient Clinic (CBOC), Rutherfordton, NC. Specifically, two identified physicians were allegedly being forced to prescribe narcotics (opioids)[1] to patients that they only see once per year.

Background

The CBOC is one of three community clinics providing outpatient care under the Charles George VA Medical Center (facility), Asheville, NC, a 119-bed acute care facility. Together with the CBOCs, the facility provides comprehensive care through a spectrum of primary care, tertiary care, and long-term care in areas of medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, and geriatrics. The facility is affiliated with the Duke University School of Medicine in Durham, NC, and is part of Veterans Integrated Service Network (VISN) 6.

The CBOC provides primary care integrated with mental health services through face-to-face visits and telephone care with three full-time physicians and clinical support teams consisting of registered nurses, licensed vocational nurses, and administrative clerks. The CBOC is also staffed with a psychiatrist, a psychologist, and licensed clinical social work staff. The CBOC, located 52 miles from the facility, operates on a full-time basis[2] and provides care for more than 3,351 unique veterans.

Veteran Health Administration's Pain Management Efforts and Opioid Safety Program

Chronic pain is a prevalent condition among veterans and can be challenging to treat. Recent changes in U.S. Drug Enforcement Administration (DEA) regulations that govern controlled substances such as opioids had a significant impact on prescribing practices. Hydrocodone, one of the most commonly prescribed opioid medications, was changed from Schedule III[3] to Schedule II[4] on October 6, 2014, requiring prescribers to write and manually sign the hydrocodone prescriptions.[5] This change resulted in the need for more frequent clinic visits, and at some VA facilities, the change in schedule also eliminated the ability of mid-level practitioners to prescribe hydrocodone.

[1] In this report, we use the term "opioids" for narcotic and opiate medications.
[2] VHA Support Service Center, *VAST Annual Classification Crosswalk of Services*. Accessed January 23, 2015.
[3] Medications that have a potential for abuse less than those in Schedules I and II; abuse may lead to moderate or low physical dependence or high psychological dependence.
[4] Medications that have a high potential for abuse which may lead to severe psychological or physical dependence.
[5] U.S. Department of Justice Drug Enforcement Administration (DOJ-DEA): Office of Diversion Control, August 22, 201421 CFR Part 1308, Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II. Accessed February 2, 2015, from http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm.

Chronic pain is described as ongoing or recurrent pain, lasting beyond the usual course of acute illness or injury or for more than 3 to 6 months and which adversely affects the individual's well-being.[6] Pain has biological, psychological, and social contributors, and treatment can be complex and require interdisciplinary interventions to address all contributors. The multifactorial nature of pain also requires individualized care for each patient, which may require referrals to several specialists. Frequent reassessments of the patient help to determine effectiveness of treatments, and the primary care provider (PCP) is often responsible for the coordination of these visits.

Veteran Health Administration (VHA) policy requires that each facility director ensure that the objectives of the VHA National Pain Management Strategy are met, including implementation of a stepped care model that provides for management of most pain conditions in the primary care setting. In doing so, clinicians are expected to meet accepted standards of care, which include pain assessment and treatment, evaluation of outcomes and quality of pain management, and clinical competence and expertise in pain management.[7]

Established on October 28, 2009, VHA's National Pain Management Strategy has several aims, including to:

1. Ensure that pain assessment is performed in an appropriately timely, regular, and consistent manner along the continuum of care from acute to chronic pain in all VHA settings.

2. Ensure that pain treatment is prompt and strives to achieve pain management objectives along the continuum of care from acute to chronic pain in all VHA settings.

3. Provide for appropriate level and frequency of monitoring for improvement in outcomes of pain management including pain control, physical and psychosocial function, quality of life, and complications.[8]

To achieve these aims, recommendations for chronic pain assessment include the following actions:

1. Review of medical history

2. Administration of a physical exam to determine baseline function and pain

3. Review prior attempts to treat pain with non-opioid modalities

4. Assessment of the risk of medication abuse through use of the opioid risk tool or consideration of any psychiatric co-morbidity

[6] American Chronic Pain Association, *Glossary*. Retrieved on July 1, 2015 from http://theacpa.org/glossary.
[7] VHA Directive 2009-053, *Pain Management*, October 28, 2009. This Directive expired October 31, 2014 and has not yet been updated.
[8] *Ibid.*

5. Determination of factors that could put the patient at increased risk for adverse outcomes[9]

The assessment of the risk of addiction and medication abuse is highly recommended. Urine drug screens (UDSs) assist providers in monitoring chronic opioid therapy (COT) patients by identifying patients using illicit substances and assisting in the diagnosis of substance use disorders. Routine and random UDSs are recommended for all patients with chronic pain prior to and during opioid therapy. Assessments determine each patient's opioid risk classification in one of three categories: low, moderate, and high. The higher the assessed risk, the more frequently UDSs should be performed.[10]

Chronic pain treatment strategies also include considering non-opioid treatment options, opioid treatment with an assessment of the patient at every visit, and re-evaluations of the treatment plan and consultation with a specialist if prescribing:

1. More than 120 mg morphine equivalents/day[11] without obvious functional improvement

2. Opioids with benzodiazepines and/or marijuana

3. Opioids to patients with respiratory disorders

Clinical practice guidelines are defined as "recommendations for the performance or exclusion of specific procedures or services derived through a rigorous methodological approach…."[12] A Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain was developed under the auspices of VHA and the Department of Defense (DoD) in May 2010. The scope of this guideline:

1. Addresses assessment and evaluation of chronic pain and appropriateness of opioid therapy

2. Presents and discusses formal treatment plans and treatment agreements

3. Provides guidance on assessing response to treatment, and determinations of adherence or abuse (aberrant drug-related behaviors)[13]

VHA's National Pain Management Program office convened a national task force comprised of multidisciplinary pain experts to create an Opioid Safety Initiative (OSI) Toolkit to help guide VHA facilities and CBOCs. The toolkit, released on October 1, 2014, consists of documents and presentations that aid VHA providers in

[9] Department of Veterans Affairs (VA) and Department of Defense (DoD), May 2010. *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain.*
[10] Charles George VA Medical Center, June 2, 2014. *VAMC Memorandum 637-11-126: Opioid Medication Use.*
[11] In order to compare dosage of pain medications, a standardized measure based on morphine has been developed and was used for this report. This is referred to as "morphine equivalents per day" or "MED."
[12] Department of Veterans Affairs (VA) and Department of Defense (DoD), May 2010. *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain.*
[13] *Ibid*.

their clinical decisions about starting, continuing, or tapering opioid therapy and other challenges related to safe opioid prescribing.[14]

Challenges of Treating Patients with Chronic Pain

Opioids are an important part of pain management, but they are also associated with serious adverse effects. Previously, providers were criticized for prescribing opioids too sparingly, and this led to a permissive opioid-prescribing environment. However, overdose deaths involving prescription opioids have quadrupled since 1999. In 2014, more than 14,000 people died from overdoses involving prescription opioids.[15] With increasing opioid overdose deaths, the emphasis on opioid prescribing has shifted to opioid dose reduction and increased assessment and monitoring of patients on COT.

Clinicians have also moved away from prescribing opioids for the treatment of chronic pain in recent years because well-designed clinical studies to determine the effectiveness of long-term opioid therapy are lacking.[16] Additionally, clinicians vary widely in their COT prescribing practices. An observed geographic variation cannot be accounted for even when taking into account other factors such as the healthcare utilization of the population. This suggests that there is little agreement regarding the appropriate use of opioids for treating pain, especially chronic non-cancer pain.[17]

Lastly, the development of an effective pain management regimen for each patient can require significantly increased time and effort. When tapering opioids, a PCP may refer patients to specialists or order non-pharmacologic treatment such as physical therapy or complementary and alternative pain management approaches. The PCP is responsible for timely reassessments and treatment plan adjustments based on patients' responses to these referrals. Customizing each patient's pain management regimen requires multiple appointments.

Patient Aligned Care Team Staffing

In early 2009, VHA adopted and customized the patient-centered medical home model of care and branded this model as the Patient Aligned Care Team (PACT). In implementing this model of care, VHA established team-based strategies that require staff coverage arrangements be done to ensure continuity of and access to care.

Specifically, local service-level officials accountable for PACTs must establish and implement written processes for coverage of PACT staffing as well as contingency plans to ensure that patients will receive needed primary care during periods of

[14] VHA Opioid Safety Initiative Toolkit, October 1, 2014. Retrieved from http://vaww.va.gov/painmanagement/ on January 23, 2015.
[15] Centers for Disease Control and Prevention. Retrieved from http://www.cdc.gov/drugoverdose/data/overdose.html on August 23, 2016.
[16] Chou R, Turner JA, Devine EB, Hansen RN, Sullivan SD, Blazina I, Dana T, Bougatsos C, Deyo RA. The effectiveness and risks of long-term opioid therapy for chronic pain: a systematic review for a National Institutes of Health pathways to prevention workshop. *Ann Intern Med.* 2015 Feb 17;162(4):276–86.
[17] McDonald DC, Carlson K, Izreal D. Geographic Variation in Opioid Prescribing in the U.S. *J Pain.* 2012 Oct;13(10):988–96.

inadequate resources, extended staff absences, staff turnover, understaffing, and nature-related events. Contingency plans must include systems that:

1. Identify a cadre of qualified, and if necessary, credentialed and privileged staff willing to assume coverage responsibilities on short notice (for example, on-call staff). Strong contingency plans include systems for continuous recruitment and hiring of PACT staff, using temporary staff, or employing permanent replacement staff.

2. Incorporate processes that estimate future hiring needs, such as monitoring panel sizes, predicting supply and demand, and assessing unmet staffing needs and gaps in care.

3. Incorporate flexible options for delivering care.

4. Reassign or redistribute patients to another PACT when the:

    a. PCP has discontinued employment with the clinical service or program accountable for the PACT;

    b. PCP is not permitted by state or federal law, or VHA or local policy, to provide health care to patients; or

    c. PCP's absence is expected to extend longer than 6 months.[18]

Allegations

On January 16, 2015, the OIG received allegations from an anonymous complainant regarding inappropriate opioid prescribing practices. Specifically, the complainant alleged that two physicians at the CBOC were being forced to write opioid prescriptions for patients who were only seen once a year.[19] While clarifying the allegations and conducting interviews onsite, we reviewed other issues related to pain management processes.

Scope and Methodology

We reviewed VHA and local policies as well as relevant facility documents, which included performance improvement data for VHA's opioid safety initiative. We conducted a site visit February 10–11, 2015, and toured the CBOC. We interviewed facility and CBOC leadership, providers, nursing, pharmacy, social work, and clerical staff. We also reviewed the electronic health records (EHRs) of a non-random sample of 26 COT patients who were assigned to the newer of the 2 CBOC PCPs mentioned in

[18] VHA Handbook 1101.10, Patient Aligned Care Team (PACT) Handbook, February 5, 2014.
[19] Initial allegations named two CBOC physicians who felt pressured by administrators to write prescriptions for dangerous amounts of narcotics without any patient evaluation. Upon interviewing the physicians, only one had concerns about system processes that did not allow for timely reassessments before subsequent prescriptions were written.

the allegation and had been prescribed an opioid medication before December 31, 2014. The sample consisted of 1 patient who was used to pilot our data analysis method, 5 patients who were reported to us during our interviews, and 20 patients who were selected at random.

In the absence of current VA/VHA policy, we considered previous guidance to be in effect until superseded by an updated or re-certified Directive, Handbook, or other policy document on the same or similar issue(s).

We **substantiate** allegations when the facts and findings support that the alleged events or actions took place. We **do not substantiate** allegations when the facts show the allegations are unfounded. We **cannot substantiate** allegations when there is no conclusive evidence to either sustain or refute the allegation.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

Issue 1: Allegation that Two Providers Were Forced To Prescribe Opioids for Certain Patients

We did not substantiate that CBOC PCPs were being forced to write prescriptions for opioids, as none of the PCPs or clinical support staff reported coercion. However, because COT is associated with considerable risks, including death, and there is a greater emphasis on safe prescribing, treatment must be individualized for each patient. Timely, quality assessments are essential to appropriate prescribing. In the context of COT, each clinician must exercise professional judgment to provide safe care.

We noted several barriers, including scheduling challenges that delayed patient reassessments, and confusion regarding availability of some non-pharmacological pain management options. We also acknowledged that a new provider assigned to a remote clinic location can experience challenges as he/she assumes responsibilities for a full panel of patients within a short timeframe. In this situation, the new provider must handle patient responsibilities and simultaneously acclimate to the VA care environment including its policies, procedures, and scheduling practices. These system challenges added an additional level of stress for the new provider. As a consequence of these factors, at least one physician felt compelled to prescribe opioids in a manner that was inconsistent with her professional judgment; however, management did not force her to prescribe opioids.

New PCP and Full Patient Panel Assignment. As of November 2014, three full-time PCPs were assigned to the CBOC, one of whom was a new provider. This new provider was reportedly given a panel that consisted of approximately 1,100 patients, which is close to the expected panel size of 1,200 patients for a full-time PCP. During the new provider's first few months, facility leadership scheduled one-hour patient appointment slots to ease the transition into her position in accordance with VHA's policy for new providers.[20]

However, the demand for appointments exceeded availability of appointment slots, and the new provider was concerned about her ability to assess all of her COT patients timely. The modified schedule for the new provider's transition period seems to have delayed the reassessments of patients needing COT refills. According to the new PCP, she felt ready to see more patients by January 2015 but reported that leadership did not approve additional appointment slots for her schedule.

The new provider stated that on several occasions she had to write opioid prescriptions prior to completing her initial assessments of these patients. Specifically, she was asked to continue another provider's treatment regimen by refilling opioid prescriptions for patients whom she had never evaluated, and these prescriptions involved doses that she considered troubling.

[20] VHA Handbook 1101.02, *Primary Care Management Module (PCMM)*, April 21, 2009.

The new provider stated that she was comfortable with continuing prescriptions for up to a month but wanted to assess these patients in person before writing additional opioid prescriptions. She also expressed concerns about the opioid-prescribing practices of the physician who had previously managed her panel. The new provider resigned after approximately 2-1/2 months of employment.

Optimizing Prescribing Practices. VA/DoD guidelines do not address how soon a new provider assesses a patient on chronic opioid therapy; however, they do provide guidance on the frequency of follow-up visits. The new provider wanted to assess her patients within the monthly timeframe.[21] She noted that many of her new patients were on short-acting opioids for pain management, and she found no evidence in the EHR that non-opioid pain management options or long-acting opioid medications had been offered. She hoped that timely reassessments might allow her to effectively tailor pain management regimens that would consist of lower opioid dosages for these patients.

Delayed Reassessments. The local facility policy requires prescriptions for opioids to not exceed a 28-day supply.[22] Reassessments not occurring within that timeframe then result in a situation where the provider must write subsequent prescriptions without updated clinical information on the patient. In our review of the EHRs for the sampled patients, we found that eight patients were not assessed within 30 days of each patient's refill request as reported by the new CBOC provider. Of these, the new PCP, with the help of another CBOC PCP, reassessed and prescribed refills to three of the patients within 36 days. After the new PCP resigned, we found that three of the remaining five patients (Patients D–H) waited 85–90 days for their reassessments. These delays in reassessing the patients' pain management needs, depicted below in Table 1, are suboptimal, but we did not note any adverse events related to the resulting delayed assessments.

[21] The VA/DoD guidelines recommend follow-up visits at least every 2-4 weeks after any change in medication regimen and at least once every 1-6 months, so the new provider's concerns about performing monthly assessments are consistent with the guidelines.
[22] Charles George VA Medical Center, June 2, 2014. *VAMC Memorandum 637-11-126: Opioid Medication Use,* pg 2.

Table 1. Timeline of Opioid Refill Requests for Patients with Delayed Reassessments

Patients with >30 Days For Opioid Refill Requests	Date of First Refill Request	Patient Reassessment Date	Days Lapsed: Refill Request to Reassessment by New PCP	Days Lapsed: Refill Request to Reassessment by Any CBOC PCP
Patient A	12/9/14	1/12/15	34	34
Patient B	11/18/14	12/23/14	35	35
Patient C	11/17/14	12/23/14	36†	36
Patient D	12/17/14	2/12/15	(50)*	57
Patient E	12/9/14	2/11/15	(58)*	64
Patient F	12/15/14	3/10/15	(52)*	85
Patient G	12/9/14	3/6/15	(58)*	87
Patient H	11/21/14	2/19/15	(76)*	90

Source: VA OIG analysis of patient EHR

†This patient was reassessed by another CBOC PCP prior to the new PCP's resignation.

** Days reported for these patients represent time lapsed without reassessment up to the date that the new PCP resigned on February 5, 2015.*

In our EHR review, we also found that 10 of the 26 patients on the new PCP's panel had risk assessments completed. According to the facility policy[23] and OSI,[24] UDSs are to be performed annually in patients on COT assessed at the lowest risk level and more frequently at higher risk levels. We noted that UDSs for all sampled patients were performed less often than required and with no specific correlations to their assessed risk levels, and two patients had no UDSs performed.

Although we noted that all of the patients had been seen in person by a provider within the past year, we found that their follow-up contacts for opioid refills were telephone calls that did not include documentation of assessments of the patients' pain levels, functional status, or adverse effects. Although such documentation is not required, VA/DoD Guideline recommends assessments of patients' adherence with their treatment plan at every visit and telephone contact and assessments of effectiveness of treatment at 1 to 6 month intervals for patients without evidence of adverse effects or adherence problems.[25]

Difficulty in Securing COT Refills. The Rutherford County CBOC support staff reported that they receive multiple phone calls from patients requesting opioid prescription refills. The staff further reported that patients had difficulty in scheduling appointments to see their PCPs for COT reassessments and refill prescriptions because of CBOC capacity, physician staffing, and appointment scheduling processes. As a result, patients may have been left without adequate supplies of pain medications.

[23] Charles George VA Medical Center, June 2, 2014. *VAMC Memorandum 637-11-126: Opioid Medication Use*.
[24] VHA Opioid Safety Initiative Toolkit, October 1, 2014. Retrieved from http://vaww.va.gov/painmanagement/ on January 23, 2015.
[25] Department of Veterans Affairs (VA) and Department of Defense (DoD), May 2010. *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain.*

Issue 2: Improvement Needed in Pain Management and Administrative Processes

While not an allegation, we noted several clinical and administrative processes that negatively impacted the delivery of quality patient care. COT is only one component of pain management. To better assess the effectiveness of the full spectrum of pain management processes, we reviewed the clinical and administrative environment in which CBOC providers prescribed opioids and managed the pain-related needs of their patients.

Challenges for CBOC PCPs

Lack of Non-Opioid Pain Management Options. At the time of our visit in February 2015, CBOC providers reported that obtaining access to non-opioid pain management options was challenging. The facility had limited ability to provide specialty pain management services and was in the process of developing an interdisciplinary chronic pain management program. CBOC providers gave us varying responses regarding this program, its proposed services, and the planned launch.

Facility leadership confirmed the continued development of an interdisciplinary pain management program at the facility and, during our interviews, reported multiple delays in implementing the program. After our site visit, facility leadership informed us that the Veterans' Integrated Pain Management (VIPM) Clinic began seeing its first patients on March 16, 2015. The clinic provides alternatives to opioids, including:

1. Acupuncture
2. Interventional therapy (for example, injections)
3. Manipulative therapy (for example, physical manipulations by chiropractic, osteopathic, physical therapy practitioners)
4. Evaluations of patients with complex pain
5. Individual and group psychiatric care
6. Consultations with pharmacists

Facility leadership reported that they were evaluating plans for increased VIPM staffing and services in fiscal year 2016 to meet continued demands for alternative non-opioid pain management care.

Increased Administrative Demands for PCPs. VHA allows the Chief of Staff or designee to consider factors such as disease burden and other clinical needs when determining the panel size of PCPs. However, VHA policy does not specify recommended adjustment of PCPs' panel sizes for chronic pain management care.[26] Several of the staff stated during their interviews that the changes in hydrocodone-prescribing rules by

[26] VHA Handbook 1101.02.

the DEA and the reviews by oversight entities have contributed significantly to the workload.[27,28]

We noted that, in addition to the usual elements of a clinic visit, PCPs have to complete opioid agreements, opioid appropriateness forms, functional assessments of the COT patient, and review of prescription monitoring databases. While the PCPs gave mixed responses about whether they have enough resources to meet the patient demands of chronic pain management care, they universally agreed that the administrative tasks associated with prescribing COT had increased. Facility leadership acknowledged this as well.

Challenges for Parent Facility Leadership

Patient Safety in Opioid Prescribing Practices. We reviewed local facility data from April 2014 to July 2016 on opioid prescribing practices to validate facility leadership's report of improved trends in safe opioid prescribing practices. We found reductions in both absolute dosages as well as number of patients who were dispensed opioids. Because of the association between average daily dose and risk of opioid overdose deaths, we interpreted these reductions as improvements in patient safety.

Table 2 demonstrates the local improvements in pain management care as reported by the facility. The number of patients on chronic opioids, benzodiazepines, or both opioids and benzodiazepines has decreased since our visit. Compliance with the 2014 VA Opioid Safety Initiative recommendations[29] has been improving, and facility leadership continues to track these measures.

Lastly, we noted that the number of patients on two forms of higher-risk opioids (methadone[30] and hydromorphone[31]) had also decreased during this same period of time. (See the last two rows of Table 2.) We observed that the facility staff prescribed fewer high risk opioids which improve patient safety.

As further evidence of improved opioid prescribing practices, we also found that overall the number of patients on chronic opioids has decreased at almost all levels of opioid dosing (99.7 percent of patients on chronic opioids) except for a small group prescribed 500 or more morphine equivalents per day (MED).[32] (See Table 3.)

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[27] U.S. Department of Justice Drug Enforcement Administration (DOJ-DEA): Office of Diversion Control, August 22, 201421 CFR Part 1308, Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II. Accessed February 2, 2015, from http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm

[28] *VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy* (Report No. 14-00895-163, May 14, 2014).

[29] http://www.va.gov/PAINMANAGEMENT/docs/OSI_1_Tookit_Provider_AD_Educational_Guide_7_17.pdf. Accessed August 15, 2015.

[30] Methadone has the ability to induce serious cardiac arrhythmias. Additionally, non-linear pharmacokinetics and incomplete cross-tolerance make dosing challenging.

[31] Hydromorphone has elevated risks for abuse and respiratory depression due to its potency.

[32] In order to compare dosage of pain medications, a standardized measure based on morphine has been developed and was used for this report. This is referred to as "morphine equivalents per day" or "MED."

Table 2. Facility Opioid Report

Facility Report	Apr 2014	Jul 2014	Oct 2014	Jan 2015	Apr 2015	Jul 2015	Oct 2015	Jan 2016	Apr 2016	Jul 2016	% Change (Apr 2014-July 2016
Chronic Opioid Patients	3279	3246	3048	2785	2723	2757	2805	2796	2811	2766	-15.65%
Chronic BZD Patients	2385	2358	2280	2179	2101	2045	2022	1977	1936	1795	-24.74%
BZD Patients on Opioid (past 90 days)	1239	1165	1045	896	814	809	801	740	703	575	-53.59%
% Urine Drug Screens (< 1 yr)[33]	47.97	53.97	59.71	75.3	80.54	79.83	78.61	84.76	87.23	92.7	93.25%
% Contract Agreement (< 2 yrs)[34]	71.85	75.88	79.13	84.78	87.88	88.28	88.52	88.45	89.15	85.07	18.40%
% Prescription Drug Monitoring Program (< 1 yr)[35]	5.12	5.45	7.61	17.52	27.87	28.87	33.87	56.04	66.81	77.95	1422.46%
Hydromorphone Patients	39	31	23	24	37	29	34	24	25	30	-23.08%
Methadone Patients	72	66	70	64	61	60	55	55	56	47	-34.72%

Source: Facility Opioid Safety Initiative Data

Note: BZD = benzodiazepine.

Table 3. Facility Report: Morphine Equivalent Per Day

Facility Report	Apr 2014	Jul 2014	Oct 2014	Jan 2015	Apr 2015	Jul 2015	Oct 2015	Jan 2016	Apr 2016	Jul 2016	% Change (Apr 2014-July 2016
< 100 MED Patients	2935	3065	2790	2807	2821	2952	2876	2773	2858	2676	-8.82%
100 - 199 MED Patients	241	248	247	254	245	241	242	230	222	186	-22.82%
200 - 299 MED Patients	86	75	74	73	73	78	79	73	61	35	-59.30%
300 - 399 MED Patients	42	43	37	34	35	30	30	27	26	14	-66.67%
400 - 499 MED Patients	13	14	14	15	8	15	9	9	8	7	-46.15%
> 500 MED Patients	8	10	6	6	5	4	8	10	11	9	12.50%

Source: Facility Opioid Safety Initiative Data

[33] The percentage of patients prescribed opioids who have had a urine drug screen performed in the past year.
[34] The 2010 VA/DoD Guideline recommends that an Opioid Pain Care Agreement that defines the responsibilities of the patient and the provider for the management of opioid therapy be established.
[35] The OSI recommends obtaining data from state prescription drug monitoring programs at least yearly and use of this information to identify patients at risk of misusing opioids.

Lastly, we reviewed the individual CBOC provider performance data for the prescribing of chronic opioids. In a comparison, the CBOC providers' performance was generally not different from those of other PCPs at the facility, and trends over the past year demonstrated reduced opioid prescribing and greater compliance with OSI requirements for all PCPs.

During our interviews, facility leaders shared that their overall sense of opioid prescribing at both the parent facility and the CBOCs had steadily improved, and this was supported by the data displayed in Tables 2 and 3. They also verbalized surprise regarding the allegations involving overly generous opioid prescribing practices concerns. Instead, they thought that perhaps they had been too aggressive in reducing opioid medications since patient complaints had increased.

Low Compliance with Benzodiazepine Appropriateness Evaluations. The prevalence of post-traumatic stress disorder (PTSD) in Gulf War, Operation Enduring Freedom, and Operation Iraqi Freedom veterans is estimated at 10.1–13.8 percent.[36] Veterans are also twice as likely to die from accidental overdoses compared to the non-veteran population. Often, they present to primary care clinics seeking relief from both physical and psychological pain. Veterans with PTSD are more likely to be prescribed opioids at higher doses, receive opioid and sedative hypnotics (including benzodiazepines) concurrently, and be at increased risk of unintentional overdose.[37]

The management of benzodiazepines and opioids is a concern because concurrent use of these two medications is generally contraindicated. During our site visit in February 2015, the CBOC PCPs stated that opioids were being prescribed by the PCPs, and benzodiazepines were being prescribed by mental health providers when patients required both medications. The CBOC PCPs stated that primary care and mental health providers ensured coordination of care by communication through progress notes in the EHR although specific delineation of responsibility was neither mentioned during interviews nor noted in our EHR reviews. This is a concern, as the OIG previously reported on a veteran who died from opioid medication overdose at a different VA facility where a lack of ongoing coordination of care was a contributing factor.[38]

According to local policy, effective September 1, 2014, patients with PTSD who are taking both benzodiazepines and opioids are required to have a Benzodiazepine Appropriateness Evaluation Note, which documents the risks and benefits of such treatment. At the time of our site visit, we noted poor compliance with this required evaluation of appropriate use of benzodiazepines for COT patients and found that

[36] Gradus, Jaimie L. January 30, 2014. VA National Center for PTSD: Epidemiology of PTSD. Retrieved June 25, 2015 from http://www.ptsd.va.gov/professional/PTSD-overview/epidemiological-facts-ptsd.asp.
[37] US Department of Veterans Affairs, Pain Management Opioid Safety: VA Educational Guide (2014). Retrieved June 25, 2015 from http://www.va.gov/PAINMANAGEMENT/docs/OSI_1_Tookit_Provider_AD_Educational_Guide_7_17.pdf.
[38] *Healthcare Inspection—Medication Management Issues in a High Risk Patient, Tuscaloosa VA Medical Center, Tuscaloosa, Alabama* (Report No. 13-02665-197, dated June 25, 2014).

facility data in February 2015 showed that only 14 of the 80 PTSD patients on benzodiazepines and opioids had such notes.

Need for Contingency Plans for PACT Staffing. We also noted inadequate PCP staffing when the new PCP abruptly resigned and left the panel of 1,100 patients without a provider. Patients were reportedly called about their clinic appointment cancellations during the first 2 days after the new PCP resigned. However, the facility had no contingency plan that would ensure continuity of and access to appropriate primary care. Reportedly, nurse practitioners (NPs) assigned at the facility were detailed to see patients in the CBOC for a period of time, but this was not sufficient to cover the needs of patients on COT. Nurse practitioners were unable to prescribe opioid medications, and the Chief of Primary Care had to fulfill this task by writing refill prescriptions for COT from the facility 70 miles away.

Inadequate Communication at Leadership Levels. During our interviews, facility leaders indicated that they were unaware of significant problems with opioid prescribing practices at the Rutherford County CBOC. Their impressions, based on facility prescribing data and provider score cards that showed Rutherford County CBOC providers' practices were generally consistent with providers assigned to other CBOC sites affiliated with the parent facility, were that the CBOC practice was similar to the facility practice and not problematic.

We noted a disconnect between the facility and CBOC leadership groups, and communication could be improved. Both facility and CBOC leadership admitted that in retrospect, better communication between the two leadership groups would have improved patient care and increased awareness of and allowed for a more effective response to the new provider's concerns.

Conclusions

We did not substantiate that CBOC physicians were being forced to write prescriptions for opioids, as none of the PCPs or clinical support staff reported coercion. However, we noted several barriers that led to delayed patient reassessments and less than optimal pain management care.

We found that at least one physician felt compelled to continue another provider's treatment regimen without reassessing patients. The physician, who had recently assumed a full panel of patients, was expected to write continuing opioid prescriptions for patients whom she had never evaluated, and these prescriptions involved doses that she considered troubling. Processes at the clinic did not allow for optimized prescribing practices, timely reassessments, or efficient COT refills. The provider ultimately resigned after approximately 2-1/2 months of employment.

We also identified challenges to the provision of outpatient COT, including the clinical environment in which providers prescribed opioids and managed the pain-related needs of their patients. Non-opioid options for outpatient pain management care were lacking, and despite the opening of the VIPM Clinic at the parent facility since

our site visit, facility leaders have evaluated plans for increased staffing and services for fiscal year 2016.

Lastly, due to new regulatory requirements, we found increased administrative demands for PCPs caring for COT patients. We noted that patient safety efforts for opioid prescribing practices resulted in improvements. However, leadership needs to develop proactive organizational solutions to address the increased administrative work required in the care of COT patients so that consistent monitoring and timely patient reassessments and prescription refills can occur. Facility leadership and PCPs also need to improve compliance with the required benzodiazepine appropriateness evaluations for COT patients with PTSD, develop staffing contingency plans that would adequately meet the needs of COT patients, and establish consistent communication channels that ensure optimal administrative support for consistent quality care.

Recommendations

1. We recommended that the Facility Director ensure that primary care providers are able to assess, treat, monitor, and reassess patients on chronic opioid therapy within the appropriate timeframe.

2. We recommended that the Facility Director ensure that the Veterans' Integrated Pain Management Clinic meets non-opioid pain management needs of patients as evidenced by timely consultation completions.

3. We recommended that the Facility Director consider the clinical and administrative demands of chronic opioid therapy care when determining appropriateness of primary care provider staffing and that staffing plans are in place for planned and unplanned provider vacancies and absences.

4. We recommended that the Facility Director ensure that benzodiazepine appropriateness evaluations are completed as required for chronic opioid therapy patients with post-traumatic stress disorder.

5. We recommended that the Facility Director ensure that primary care and mental health providers communicate and coordinate care for post-traumatic stress disorder patients receiving both opioids and benzodiazepines.

6. We recommended that the Facility Director ensure regular communication between facility leadership and community based outpatient clinic leadership to support consistent high quality care.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: January 11, 2016

From: Director, VA Mid-Atlantic Health Care Network (10N6)

Subject: Healthcare Inspection—Alleged Inappropriate Opioid Prescribing Practices, Rutherford County CBOC, Rutherfordton, North Carolina

To: Director**,** OIG Office of Healthcare Inspections, Community Based Outpatient Clinics Review Program (54F)

Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. Attached, please find the updated report of the review of the Alleged Inappropriate Opioid Prescribing Practices, Rutherford County CBOC, Rutherfordton, North Carolina.

2. I have reviewed and concur with the completed response.

3. I appreciate the Office of Inspector General's efforts to ensure high quality care is provided to the Veterans at the Rutherford County CBOC.

4. For further inquiries, please contact Lisa Shear, QMO at (919) 956-5541.

(original signed by:)
Daniel F. Hoffman, FACHE
Network Director, VISN 6

Appendix B

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: January 12, 2016

From: Director, Charles George VAMC, Asheville, North Carolina (637/00)

Subject: Healthcare Inspection—Alleged Inappropriate Opioid Prescribing Practices, Rutherford County CBOC, Rutherfordton, North Carolina

To: Director, VA Mid-Atlantic Health Care Network (10N6)

1. Thank you for the opportunity to review the report of the Alleged Inappropriate Opioid Prescribing Practices, Rutherford County CBOC, Rutherfordton, North Carolina.

2. I have reviewed the document and concur with the recommendations. Relevant action plans have been established as detailed in the attached report. Below please find the facility concurrence and response to the findings from the review.

3. If you have any questions or need further information, please contact Robin James, Chief Quality Management at (828) 298-7911 Ext. 559.

(original signed by:)
Cynthia Breyfogle, FACHE
Medical Center Director, Charles George VA Medical Center

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the Facility Director ensure that primary care providers are able to assess, treat, monitor, and reassess patients on chronic opioid therapy within the appropriate timeframe.

Concur

Target date for completion: Completed

Facility response: As a part of the Opioid Safety Initiative, a new Primary Care Opioid Renewal note was implemented in February 2015. This note captures important information related to prescribing chronic opioid therapy such as drug name, last note documenting a query of the state prescription drug monitoring program and last urine drug screen. Primary Care Service will perform monthly chart audits of a sample of patients prescribed chronic opioids to ensure that the assessment, treatment, monitoring and reassessment of patients occurs within the appropriate timeframes.

Recommendation 2. We recommended that the Facility Director ensure that the Veterans' Integrated Pain Management Clinic meets non-opioid pain management needs of patients as evidenced by timely consultation completions.

Concur

Target date for completion: Completed

Facility response: Veterans Integrated Pain Management Clinic staff worked with System Redesign Coordinators to analyze processes and develop improvements to increase scheduling efficiency and timeliness. This group identified persistent demand exceeding supply, particularly for acupuncture. Proposals for augmented staffing are being developed and will be implemented. Consult completion timeliness will continue to be monitored on a monthly basis.

Recommendation 3. We recommended that the Facility Director consider the clinical and administrative demands of chronic opioid therapy care when determining appropriateness of primary care provider staffing and that staffing plans are in place for planned and unplanned provider vacancies and absences.

Concur

Target date for completion: Completed

Facility response: Primary Care physician positions will be fully staffed by the end of January 2016 when the last of the three Gap physician position will be filled. This will result in a ratio of one Gap physician for every 10 primary care panels. This will allow for coverage for planned and unplanned leave without disrupting chronic opioid therapy requirements, in addition to all other patient care requirements. When an absence at a CBOC occurs, this will also allow a detail of a physician to cover until a replacement physician can be recruited.

Recommendation 4. We recommended that the Facility Director ensure that benzodiazepine appropriateness evaluations are completed as required for chronic opioid therapy patients with post-traumatic stress disorder.

Concur

Target date for completion: Completed

Facility response: The Opioid Safety Initiative staff continues to work with both Primary Care Service and Mental Health Service to complete the evaluations for the opioid therapy patients receiving benzodiazepines. As of the end of December, 65% of patients had a completed evaluation. The remaining patients in need of a note have been identified and shared with the appropriate service chief to ensure completion. This monitoring will continue until compliance is achieved.

Recommendation 5. We recommended that the Facility Director ensure that primary care and mental health providers communicate and coordinate care for post-traumatic stress disorder patients receiving both opioids and benzodiazepines.

Concur

Target date for completion: Completed

Facility response: Both the Chief, Primary Care (PC) Service and the Chief, Mental Health (MH) Service educated the staff on the importance of provider to provider communication to coordinate care for post-traumatic stress disorder (PTSD) patients receiving both opioids and benzodiazepines. Additionally, staff of both services were reeducated through periodic Opioid Safety Initiative updates, and will continue to emphasize the importance of this communication and care coordination.

A template with the title “PTSD Medication Coordination note” is being created and will be completed by Mental Health (MH) and Primary Care (PC) for all Veterans that have a diagnosis of PTSD and who are prescribed both opioids and benzodiazepines. The template will reflect documentation of the communication and coordination of care. For the Veterans that the MH and PC are in agreement, treatment will continue as outlined. For those Veterans where the MH and PC providers do not agree, the case will be referred to the Opioid Safety Review Board for follow up.

The current population that fits this category of having a diagnosis of PTSD, being prescribed opioids and being prescribed benzodiazepines is approximately 290. A

100% review will be completed to ensure that communication and coordination is documented on the "PTSD Medication Coordination note" for all Veterans in this category. An excel report was created and will be run monthly that identifies new cases that fit in this population. The new cases will be reviewed as previously specified.

Recommendation 6. We recommended that the Facility Director ensure regular communication between facility leadership and community based outpatient clinic leadership to support consistent high quality care.

Concur

Target date for completion: Completed

Facility response: Every Wednesday during leadership morning report, each CBOC reported on Quality Measures, workload, patient satisfaction scores, access, staffing vacancies affecting productivity, and other quality oversight data. These communications have ensured regular communication between the facility leadership and the community based outpatient clinic leadership to support consistent high quality care.

Appendix C

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	Mary Toy, RN, MSN, Team Leader Larry Ross, Jr., MS Robert Yang, MD Marilyn Stones, BS

Appendix D

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Director, VA Mid-Atlantic Health Care Network (10N6)
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